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JUL 22 2002

Ms. Sindy Filippone  
Edge Labs, Inc.  
470 Rout 9  
Englishtown, New Jersey 07726

Dear Ms. Filippone:

This is in response to your letters of June 13, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions state that Edge Labs, Inc. is making the following claims, among others, for the following products:

**SOY FOR HEART**

“Two servings of Soy for Heart, as part of a diet low in saturated fat and cholesterol, supply the 25 grams of soy protein that, if taken daily, may reduce the risk of heart disease.”

**Calcium Connection**

“Building and maintaining good bone health can reduce the risk of osteoporosis. Those most at risk are teens, young adult white and Asian women. Adequate calcium intake along with proper exercise can help reduce the risk of this disease. The recommended daily dosage is 1000mg. Intake of over 2000mg of calcium per day has no further known benefit to bone health.”

These statements are not statements of nutritional support subject to 21 U.S.C. 343(r)(6), but are health claims subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized health claims on the relationships between calcium and osteoporosis (see 21 CFR 101.72) and soy protein and risk of coronary heart disease (see 21 CFR 101.82). A dietary supplement that meets the eligibility and message requirements set forth in these regulations may bear a claim for the relationship between the subject dietary substances and diseases. A health claim for either calcium or soy protein on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 or 21 CFR 101.82, respectively, would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in 21 CFR 101.72 or 21 CFR 101.82 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, namely, osteoporosis or coronary heart disease, respectively.

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Your submission for **SOY FOR HEART** also states that Edge Labs, Inc. is making the claims "Homocysteine build up has been associated with an increased risk of heart disease" and "Vitamins B6, B12 and Folic Acid have been linked with reducing levels of homocysteine in the blood."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease, namely, coronary heart disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C.

321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,



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Director

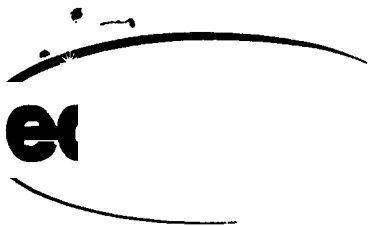
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

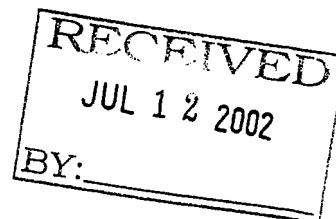
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New Jersey District Office, Office of Compliance, HFR-MA340



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6/13/02

Office of Nutritional Products, Labeling and  
Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

**SECTION 403(r)(6) NOTIFICATION**

RE: **CARB OUT**

Dear Sir or Madam:

In accordance with the requirements of section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act, EDGE LABS INC. notifies FDA that it has begun using the following statements regarding a standardized white kidney bean extract and a combination of chromium and biotin in a patented formula:

"Carb Out is desianed to be taken before meals usina Phase 2™ a clinically proven carbohvdrate inhibitor and Diachrome™, a Patented product developed to aid in glucose metabolism."

"C Out performs in your stomach as your body goes to work digesting food."

"Carb Out is a uniaue formula that taken during a meal is designed to intercent the body's absorption of calories from carbohvdrates."

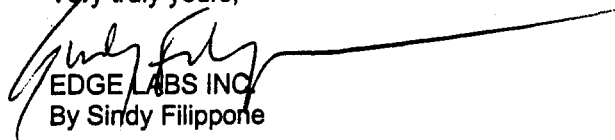
"Each delicious servina works in the stomach to intercent the body's absorption of carbohvdrates aid in the metabolism of glucose and curb sugar cravings."

Which contain the statutory statement, on the following product:

**Carb Out**

I certify that the foregoing is complete and accurate, and that EDGE LABS has substantiation that the statements are truthful and not misleading.

Very truly yours,

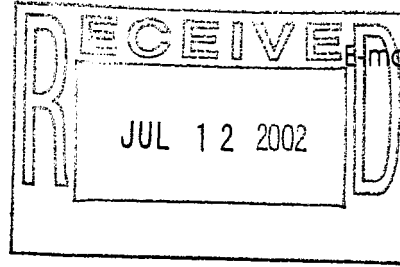
  
EDGE LABS INC.  
By Sindy Filippone

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Dietary Supplements (HFS-800)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

**SECTION 403(r)(6) NOTIFICATION**

RE: SOY FOR HEART

Dear Sir or Madam:

In accordance with the requirements of section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act, EDGE LABS INC. notifies FDA that it has begun using the following statements regarding soy protein and the B vitamins B6, B12 and folic acid:

" w servings of Sov for Heart. as Dart of a diet low in saturated fat and cholesterol, supply the 25 a grams of soy protein that if taken daily may reduce the risk of heart disease."

"Homocysteine build up has been associated with an increased risk of heart disease."

"Vitamins B6, B12 and Folic Acid have been linked with reducing levels of homocysteine in the blood."

"S is a rich source of isoflavones and saponins. naturally occurring plant antioxidants that have shown a positive effect on heart health."

Which contain the statutory statement, on the following product:

SOY FOR HEART

I certify that the foregoing is complete and accurate, and that EDGE LABS has substantiation that the statements are truthful and not misleading.

Very truly yours,

  
EDGE LABS INC.  
By Sindy Filippone

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